IRMA Support Manual
Up to and Including Software Version 5.1.x

(Note: This is a controlled document. All changes must be authorized by DMI and revision controlled. This document is not intended for customer use.)

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Question & Answer Section

Subject	Question	Answer
Quality Control	What kind of aqueous quality control material may be used on IRMA?	DMI recommends and supports RNA Medical Quality Control materials. Other aqueous quality control materials that contain physiological levels of electrolytes may work with the IRMA system, but customers will be required to establish their own ranges. Philips/DMI Technical Support can only provide limited AQC support on non-RNA controls.
	How do I obtain Aqueous Quality Control Ranges?	IRMA Quality Control ranges for all RNA Medical quality control material are available on the DMI website at: http://www.diametrics.com/RNA_QC_and_Linearity.htm Ranges can also be obtained by contacting the Philips Response Center or DMI Technical Support.
	How should aqueous quality control material be handled?	Follow the instructions provided with the DMI quality control ranges. You can view these on the DMI website at: http://www.diametrics.com/RNA_QC_and_Linearity.htm **See Appendix A.**
	How should the aqueous quality control material be stored?	RNA QC materials do not require refrigeration. Follow manufacturer's recommendation for storage. If material is refrigerated, allow material to warm to room temperature for a minimum of four hours prior to use.
	How is a quality control range determined?	Follow instructions provided by DMI. **See Appendix B.**
	What is Electronic Quality Control?	**See Appendix C.**

IRMA Hardware		
Battery	How long will the batteries last?	NiMH batteries will allow 30-40 tests depending on the features activated and how many printouts are required.
	How long does the battery take to charge?	2-10 hours, depending on battery type, its condition and existing charge. Be sure to leave the battery in the charger until the green LED flashes continuously. The green LED on the charger will begin to blink (blinks for 30 seconds, off for 4 seconds, blinks for 30 sec. Etc.) when the battery is at approx. 90% capacity. When it reaches 100% capacity the green light will blink continuously. Batteries should remain in the charger until the green LED blinks continuously.
Paper	Can any paper be used in IRMA?	No. Philips sells the only paper type recommended for use in IRMA.

Barometric Pressure	Is the barometric pressure switch active in IRMA?	Yes, IRMA uses an active barometer that is constantly measuring the barometric pressure.
	How often should the barometer be calibrated?	Annually, using a National Institute of Standards and Technology (NIST) traceable barometer. Adjust the IRMA barometer if it is not within ± 5 mmHg of the NIST barometer reading. *Do not use a water barometer*, ***or airport barometric pressure readings***.

IRMA	How much does IRMA weigh?	5 pounds, 4 ounces
	What is IRMA's size?	11.5"x 9.5"x 5"
	What is IRMA's operating temperature?	IRMA v 5.0 and higher: 12-30ºC (54-86ºF) IRMA v 4.x.x and lower: 15-30ºC (59-86ºF
	What is the humidity range for IRMA?	0-80% relative humidity
	How is IRMA's software upgraded?	Software updates are performed by connecting IRMA's RJ45 serial port (on IRMA it is labeled computer port) to a PC's serial com port. The updated software is loaded onto the PC from a floppy disk provided by DMI. The software is then uploaded to IRMA from the PC through the serial connection.

Evaluations	Where is the best location to place IRMA?	IRMA should be set up next to the reference analyzer to minimize any time delay between sample analysis on the two instruments and to insure that the sample is treated the same for both analyzers.
	What is the best sample type to use on IRMA?	Whole blood collected in a lithium heparin or balanced heparin syringe.
	Who should perform the evaluation?	Laboratory personnel who have been properly trained on IRMA and are familiar with the reference analyzers.
	What type of quality control program should be used during the evaluation?	Use the quality control program established in the institution for the reference analyzers. For IRMA, use both Electronic Quality Control (EQC) and Aqueous Quality Control (AQC). The purpose of this is to familiarize testing personnel with the use of aqueous quality control material on IRMA and to validate the EQC system.
	Does anticoagulant need to be used?	DMI recommends the use of anticoagulant on samples used on IRMA.
	What type of anticoagulant can be used on IRMA?	DMI recommends Lithium Heparin as the anticoagulant of choice. Sodium Heparin may also be used noting that it may falsely elevate sodium results by 2 mM.(approximate). Balanced or low volume heparin is recommended for ionized calcium testing.

	What type of patient samples should be included in the method evaluation?	DMI recommends the use of patient samples from the facility's general population. During preliminary evaluation, it is not recommended that CVOR patient samples be used to evaluate hematocrit.
	What information needs to be collected?	Accuracy: Whole blood split sample study analyzing samples on a reference instrument and IRMA. Diametrics recommends a minimum of 20 samples be collected. Precision: Aqueous Quality control samples analyzed. Diametrics recommends a minimum of 10 samples per control level be collected. Linearity: Aqueous and Whole Blood linearity studies are performed on each analyte. (Required for CAP customers only).
	How is the data analyzed?	Accuracy: Determine slope, intercept, correlation coefficient, and Sy.x. Graph all analytes using linear regression and Bland-Altman plots. Precision: Determine mean, standard deviation and coefficient of variation. Linearity: Determine Correlation coefficient. Graph all analytes tested using linear regression.

Sample Handling		
Whole Blood	What type of syringe should be used for sample collection?	Most arterial lithium heparin syringes may be used on IRMA. **See Appendix D** for complete list and limitations.
	What syringe size should be used on IRMA?	Diametrics recommends a 1 or 3cc syringe for use on IRMA. For sample volumes < 400uL, DMI recommends use of 1cc syringes.
	What is the sample mixing recommendation for samples analyzed on IRMA?	In order to avoid pre-analytical error on samples analyzed for pH, ionized calcium and hematocrit, the sample should be adequately mixed (we suggest rolling between your palms). A sample that has been placed in an ice slurry should be mixed for a minimum of 2 minutes prior to injection into IRMA (NCCLS recommendation). A sample that has been drawn from a patient and will be immediately injected into IRMA still needs to be mixed (Recommend 30 seconds).

	What is the proper injection technique for whole blood into the IRMA analyzer?	Inject the sample by depressing the syringe plunger in a single, quick, controlled motion, similar to the motion used to press a stopwatch button. Initially, some resistance may be felt since the sample must displace the calibration gel. Stop injecting when the gel has been displaced and blood is covering the sensors. Slowly inject additional sample to displace bubbles, gel, or to reach the minimum sample volume of 200uL. Leave the collection device attached to the cartridge until the analysis is complete. Note: The initial injection should "pop" the calibrant out of the sample path. If you can see the blood pushing the calibrant out of the sample path, then you are injecting too slow.
Correlation	When would a customer typically decide to use the correlation option?	When there is a significant, consistent bias between IRMA and their reference analyzer for a particular analyte AND the facility routinely uses both IRMA and the reference for testing and wants them to read the same (e.g., routine batch testing on reference , STAT testing on IRMA).
	How should correlation data be collected?	Correlation factors are based on split-sample blood results from a statistically valid number of samples. Follow the instructions in Section 7 of the IRMA User Manual.
	How is the data analyzed?	Graph the reference analyzer results against the IRMA analyzer results for each set of values. Plot the results for each analyte separately. Make the reference analyzer results the Y (dependent) variable; make the IRMA analyzer the X (independent) variable. Perform linear regression analysis on the results. Delete any data points that are more than three standard deviations from the regression line. Replace them with data acquired from additional split sample analyses and re-determine the regression line.
	What are the issues with hematocrit in the CVOR?	IRMA uses conductivity to measure hematocrit. While on cardiopulmonary bypass several components of the blood may experience changes either due to interferences, or as a result of hemodilution. A complete discussion and protocol for CVOR and hematocrit measurements "Corrrecting Conductive Hematocrit Results for Hemodilution During Cardiopulmonary Bypass" is available from Agilent.
	How is the correlation feature activated?	Refer to Section 7 of the IRMA User Manual.

Alternate Site	Can IRMA be used in a transport (airplane, helicopter, ambulance) or non-hospital setting?	Yes. IRMA may be used in any setting as long as environmental conditions (i.e., temperature, BP, humidity) do not exceed IRMA specifications.
	Can IRMA and cartridges be stored in the alternate site?	No. IRMA needs to be stored in a temperature range of 15-30ºC. Most alternate site locations cannot accommodate this. The cartridges need to be stored within a STABLE temperature range of 15-30ºC that does not fluctuate more than ±8ºC. DMI recommends that both IRMA and cartridges be stored in a stable temperature environment off the alternate site location. IRMA and an appropriate number of cartridges should be taken from the storage site when testing in an alternate site is required. Cartridges that are not used during a testing event (e.g., an ambulance run) must go through the 72 hour equilibration time before being put back into use unless the site can verify that temperature fluctuations did not exceed ±8ºC of the room temperature storage area. Verification is possible if cartridges are transported and stored in an IRMA carrying case that contains a high/low thermometer.
	Where should quality control be performed?	EQC can be performed on the analyzers in the storage area or in the alternate site. AQC should be performed on the cartridges in the storage area prior to placement in the alternate site.

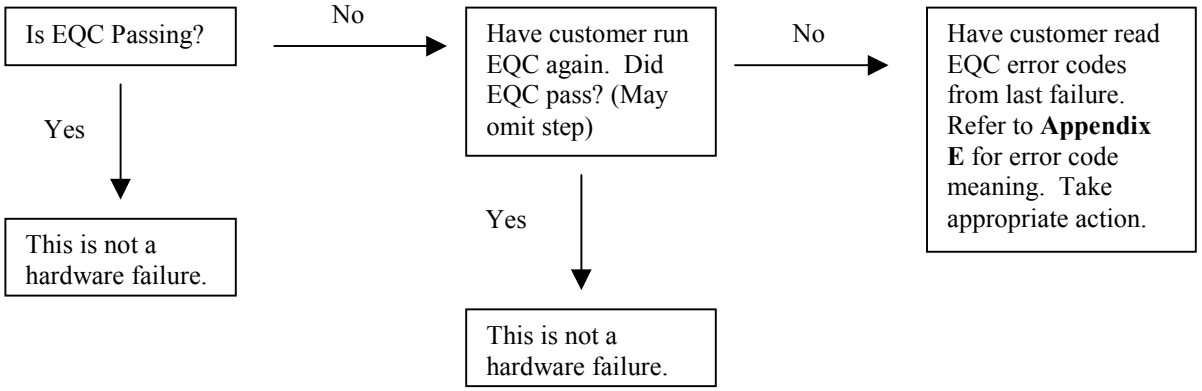
Calibration	How does IRMA calibrate?	IRMA performs a modified two-point calibration. The sensors are calibrated prior to each test using a pre-packaged calibrant over the sensors. The calibrant is manufactured and tested with NIST traceable gases and salt standards. Calibration of the cartridge is completed when information determined at the factory for each lot of cartridges (the Cal Code) is combined with measurements taken during the calibration process. The factory derived Cal Code information is stored in the analyzer memory following initial entry of a new cartridge lot.

Proficiencies	What proficiencies programs are recommended for use on IRMA?	**Appendix I**
	What are the proficiency testing requirements for CAP?	If your customer is CAP certified, they must participate in the CAP surveys. Sometime during the year, they must perform a CAP survey on every IRMA they have. CAP does not accept the idea of proving instrument comparability by running a survey on a primary instrument and split sampling on the rest. (CLIA does accept this). CAP has stated that it is acceptable to split surveys amongst multiple analyzers so those customers are not required to purchase a separate survey for each IRMA. EXAMPLE: A customer has 30 IRMA's. They order 1 blood gas proficiency. (AQ survey). They receive this survey three times a year. Each survey has at least five levels plus at least five duplicates, therefore, ten proficiency samples. They receive their first survey in January. Since they have ten samples, they analyze one on each of ten analyzers. THEY RECORD EVERYTHING AND KEEP RECORDS OF THE TESTING. They receive their next survey in June with ten more samples. They run these on ten DIFFERENT IRMAs. Ditto for the next survey received in November. If they keep good records, they can show CAP, during their inspection, that they have analyzed a proficiency sample on each of their IRMAs.

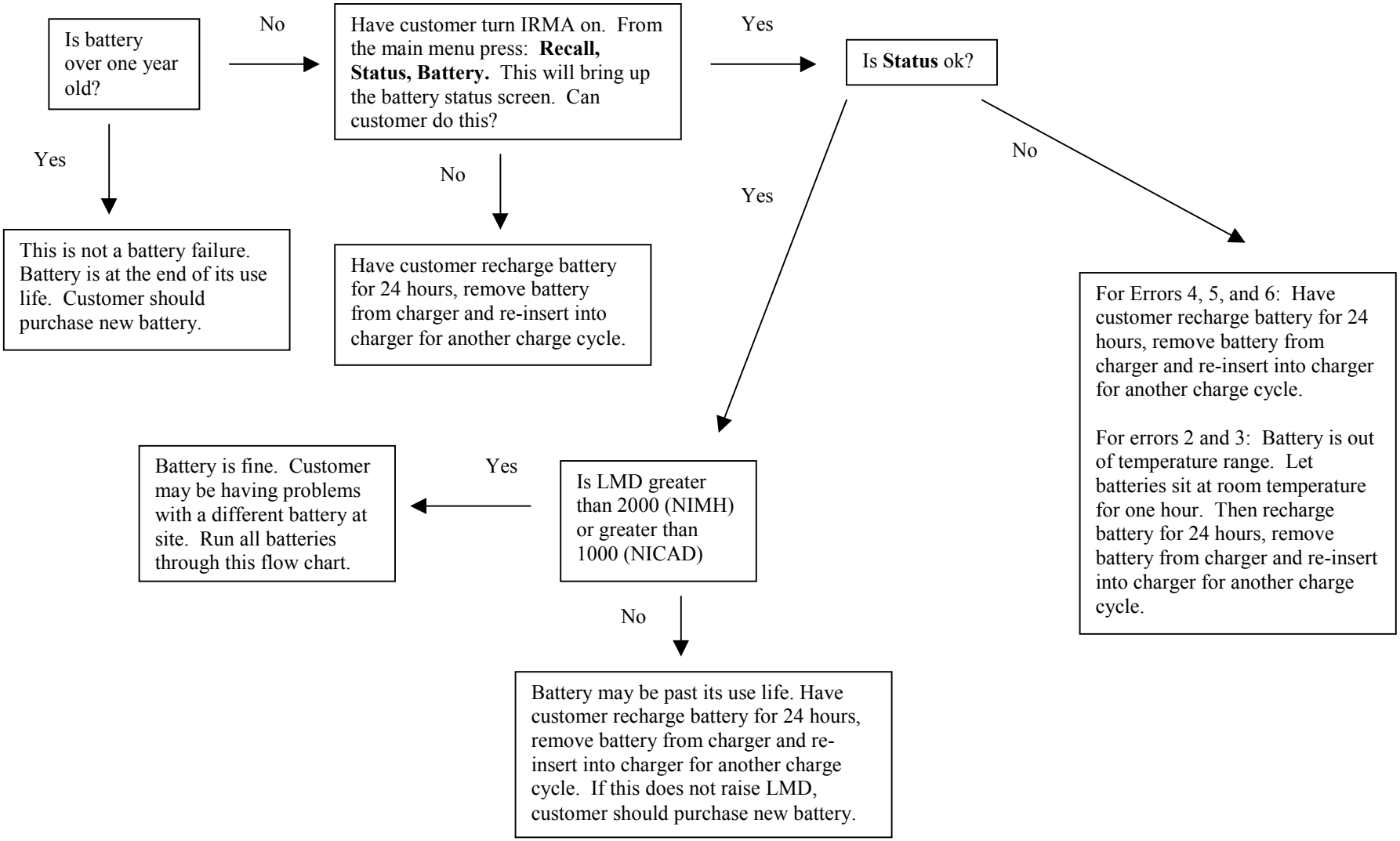
Regulatory	How do CAP, CLIA and JHACO rules and regulations compare?	**Appendix J**

Technical Section:

IRMA FAILURE:



BATTERY FAILURE:



CHARGER FAILURE:

Batteries do not fit in charger. →

Make sure that the batteries and the charger are the same type. (Note: Although NiCAD batteries can be recharged in an NIMH charger, for optimum performance we recommend keeping the same battery with the same charger).

NIMH products all have +++ on them.

NiCADs have SL on batteries and no markings on charger

Charger lights are not coming on.

Not charging batteries. →

Make sure all connections are firmly in place:

charger to power supply and power supply to cord and cord to outlet.

Yes ↓

Make sure wall outlet has power.

Yes ←

Try a different power supply and/or cord.

Yes ↓

Return charger for service.

AC ADAPTER FAILURE:

No power while using an AC Adapter.	→	Replace if still under warranty. Customer purchase new one if out of warranty.

CARTRIDGE FAILURES:

Reservoir bag broken. →

Remind customer to never use a cartridge from a pouch with a broken reservoir bag and credit account for the cartridge. Do not return to DMI for investigation. Report Lot number to DMI.

Cartridge leaking →

Is top and bottom of cartridge snapped down completely.

Is ceramic chip seated properly.

Do not return to DMI for investigation. Report lot number and manufacturing issue to DMI. Credit account for the cartridge.

Cartridge not recognized. →

Make sure customer is not inserting EQC/TEMP card in patient test mode.

Do not return to DMI for investigation. Report lot number to DMI and credit customer for the cartridge.

Sensor Errors →

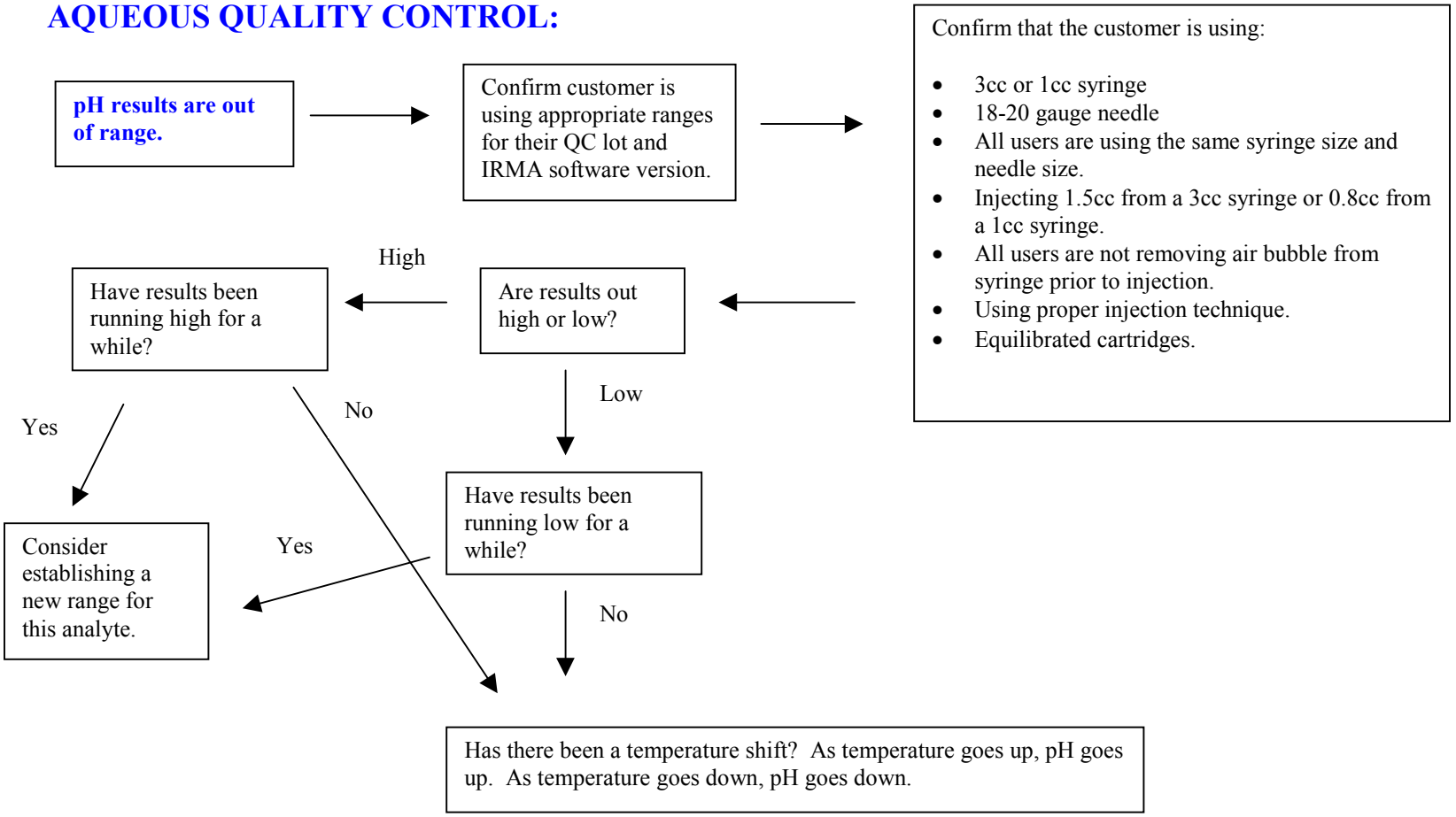
Have customer supply usage log. From **Main Menu**, press **Recall**, **Error Logs,** and **Usage.** This will print out the last 50 messages IRMA has given the user.

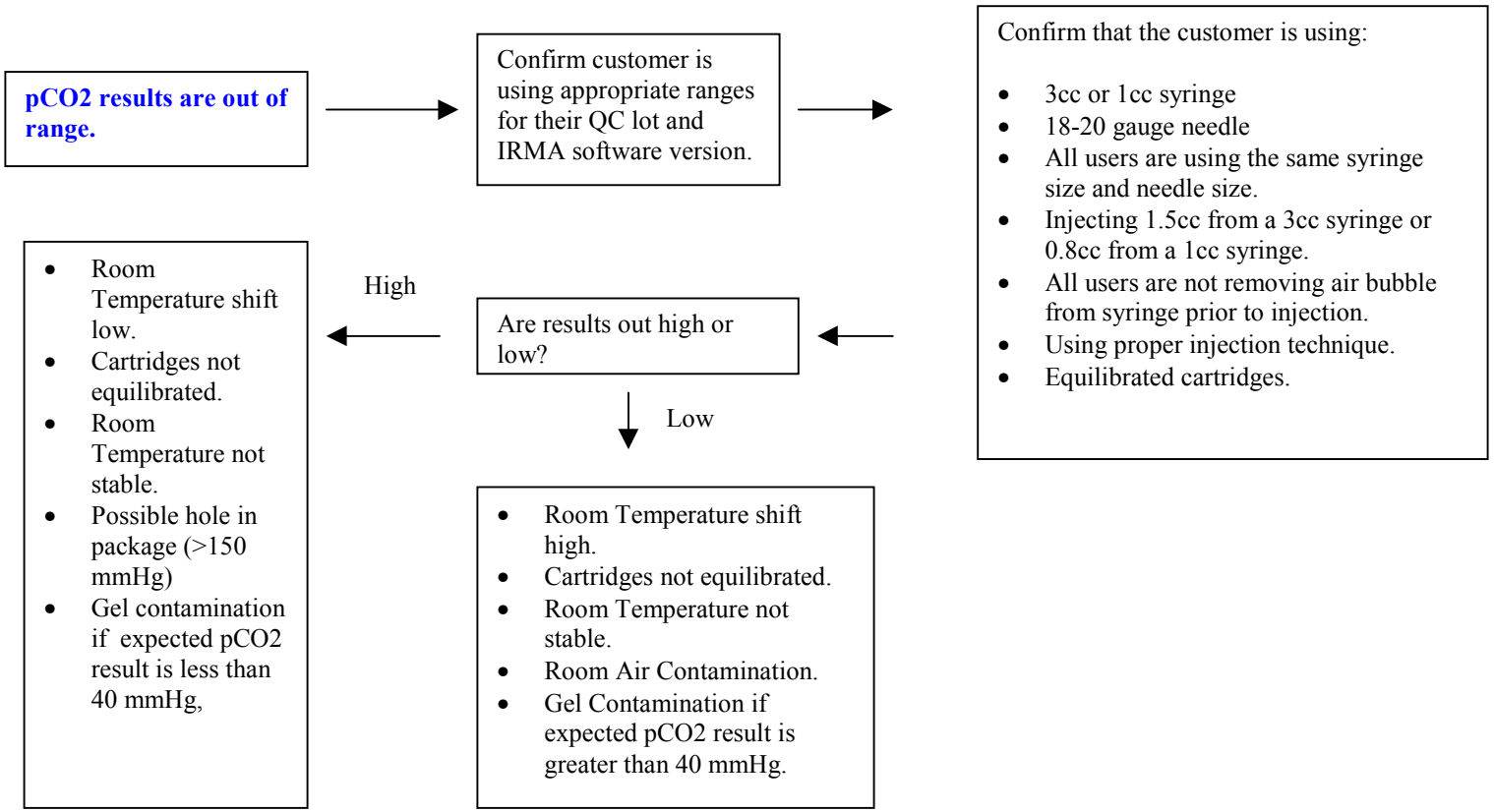
Locate all errors starting with 5xxx. These are the sensor errors.

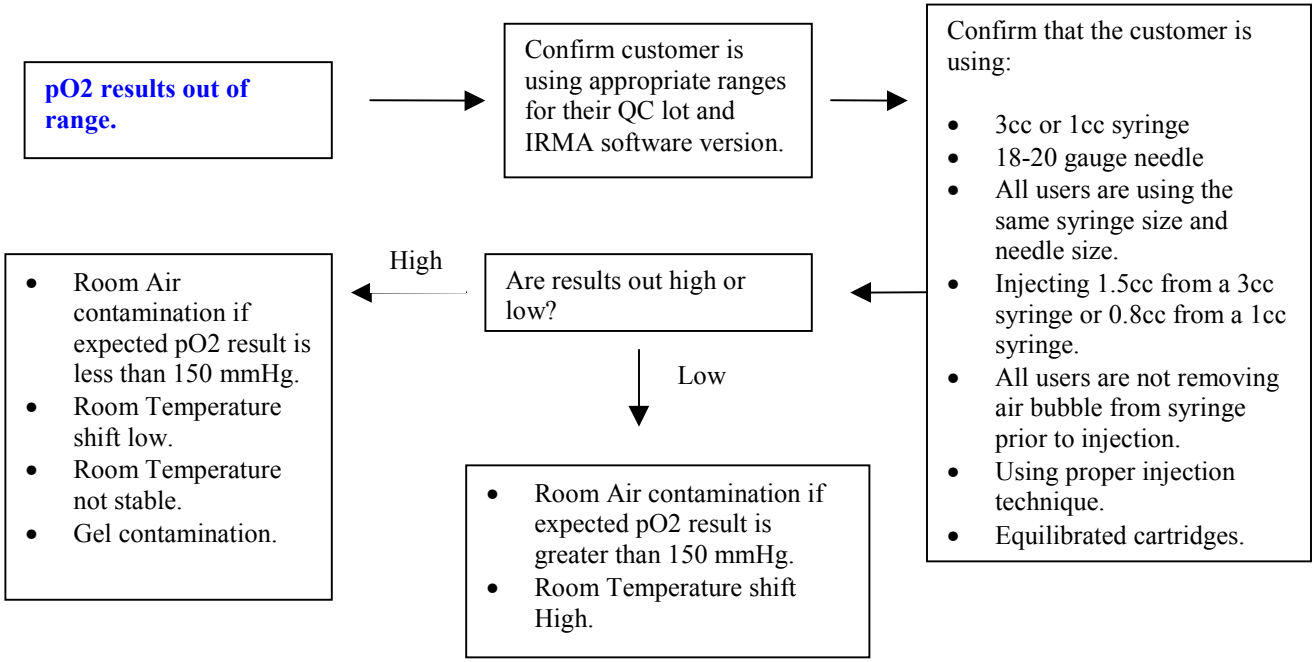
Refer to **Appendix G** for a list of sensor errors and their possible causes. Take appropriate action.

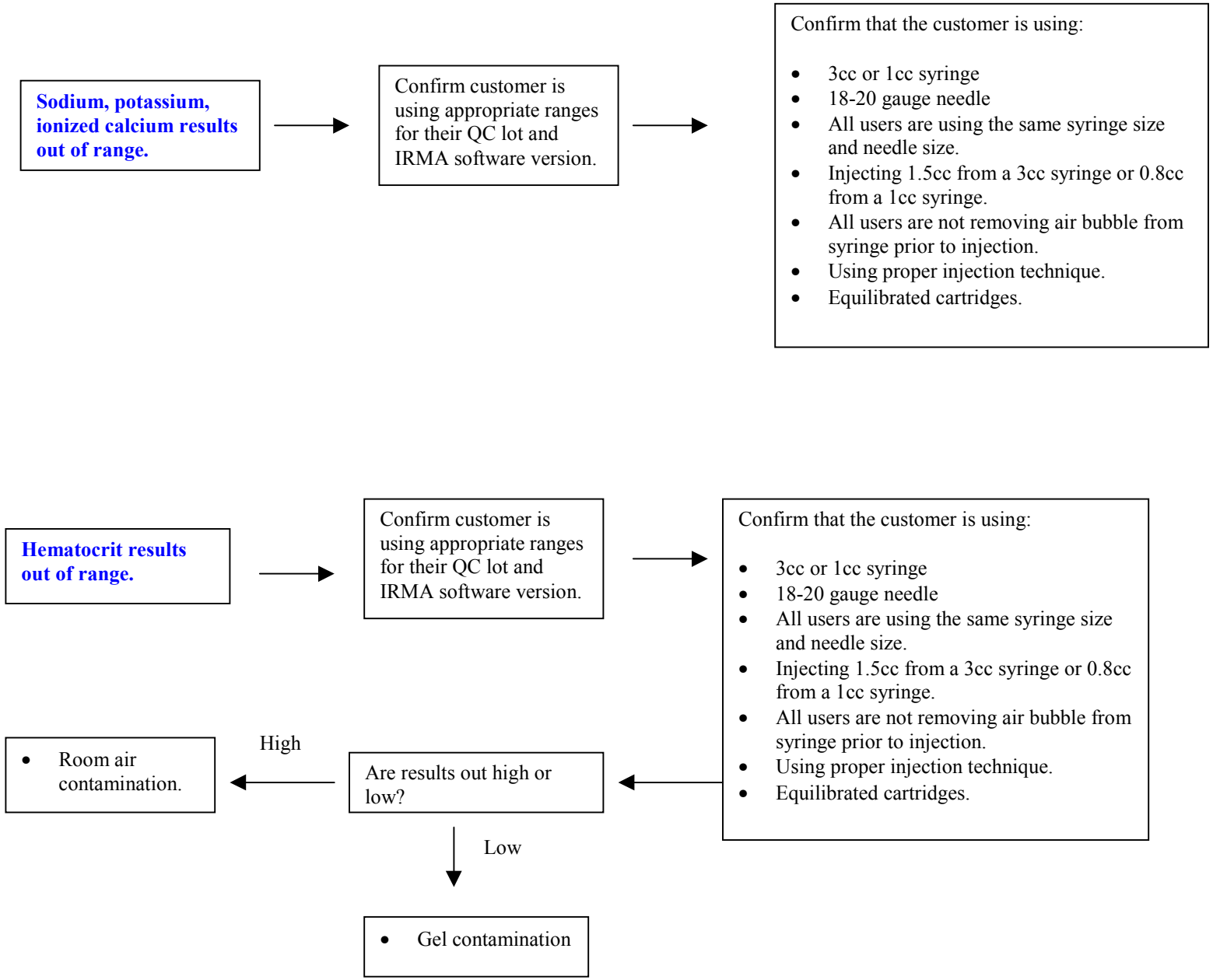
If error rate is over 10%, notify DMI with lot number and copy of usage log.

AQUEOUS QUALITY CONTROL:

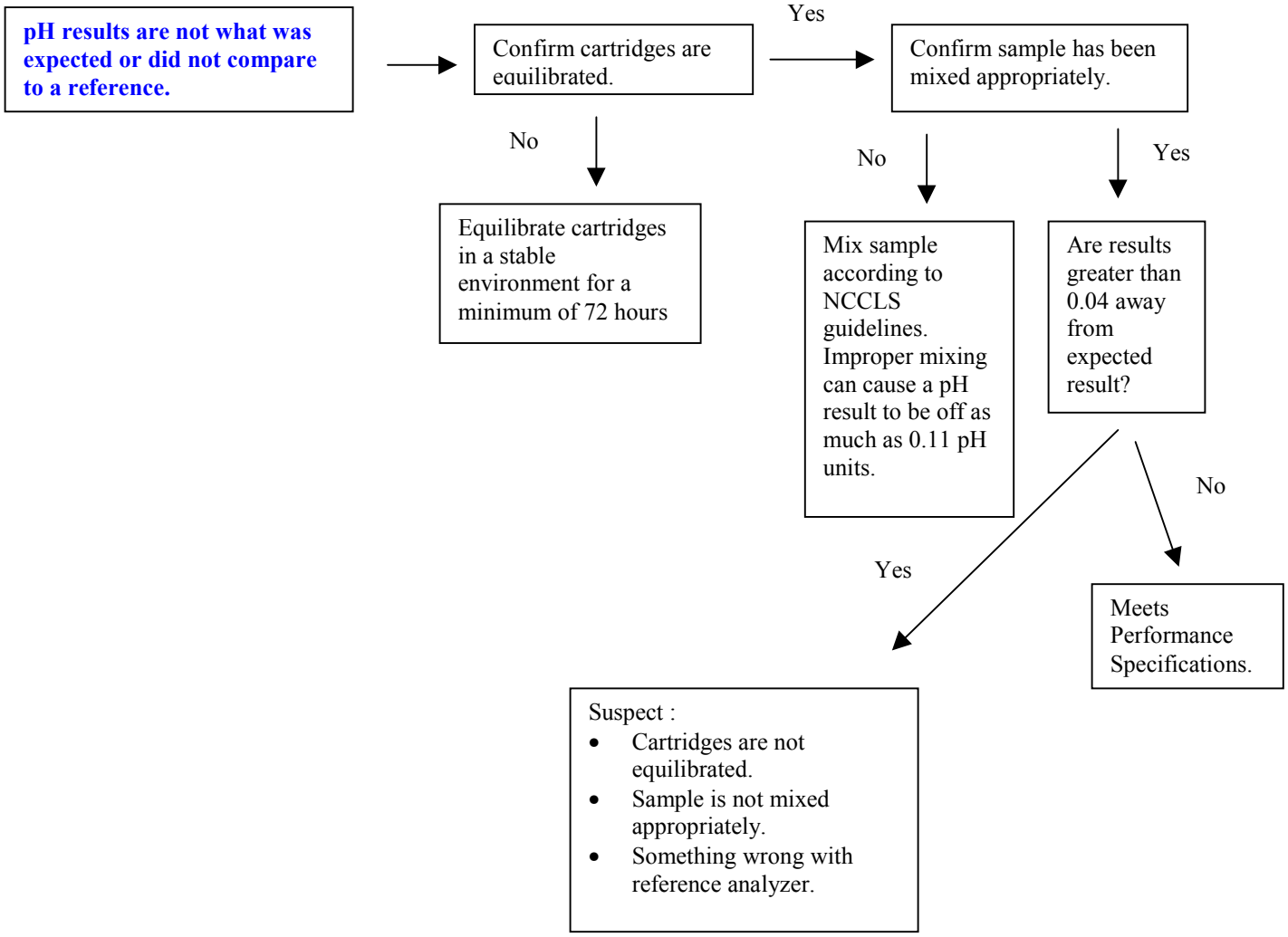


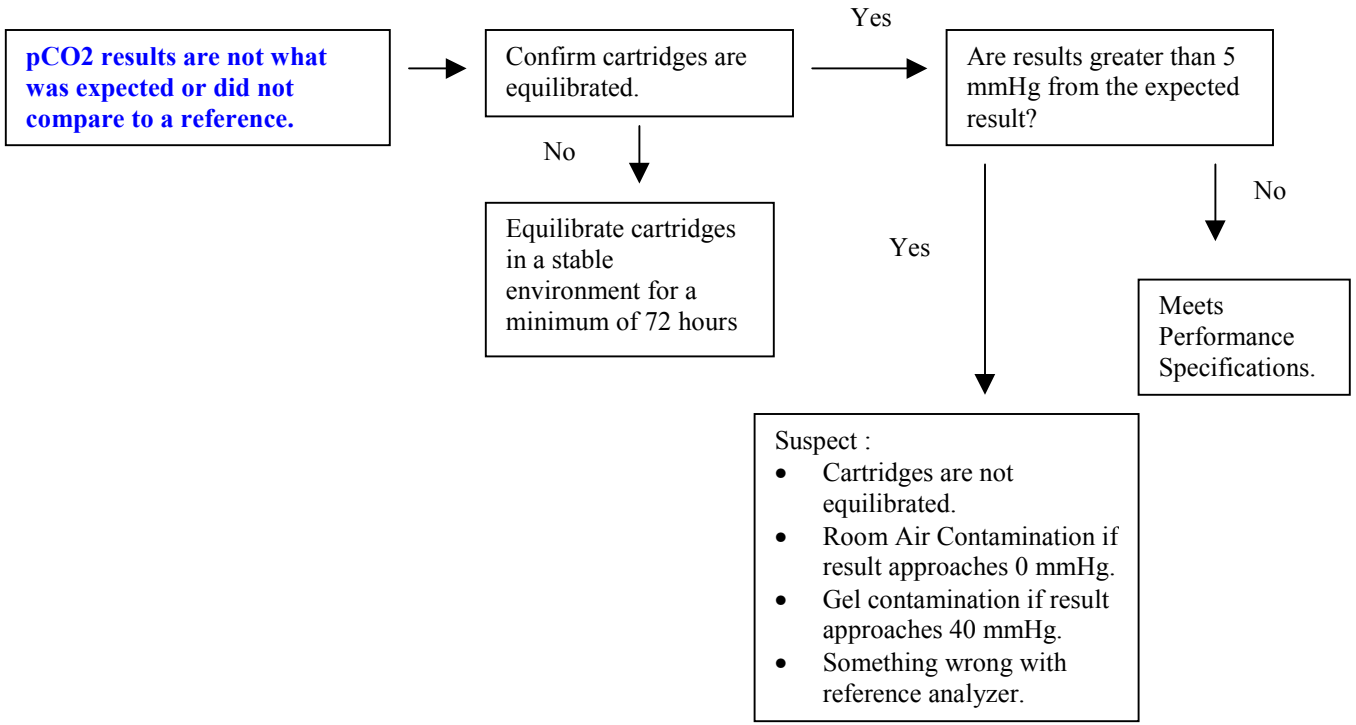

pCO2 results are out of range.
Confirm customer is using appropriate ranges for their QC lot and IRMA software version.
Confirm that the customer is using:
3cc or 1cc syringe
18-20 gauge needle
All users are using the same syringe size and needle size.
Injecting 1.5cc from a 3cc syringe or 0.8cc from a 1cc syringe.
All users are not removing air bubble from syringe prior to injection.
Using proper injection technique.
Equilibrated cartridges.
Are results out high or low?
High
Room Temperature shift low.
Cartridges not equilibrated.
Room Temperature not stable.
Possible hole in package (>150 mmHg)
Gel contamination if expected pCO2 result is less than 40 mmHg,
Low
Room Temperature shift high.
Cartridges not equilibrated.
Room Temperature not stable.
Room Air Contamination.
Gel Contamination if expected pCO2 result is greater than 40 mmHg.

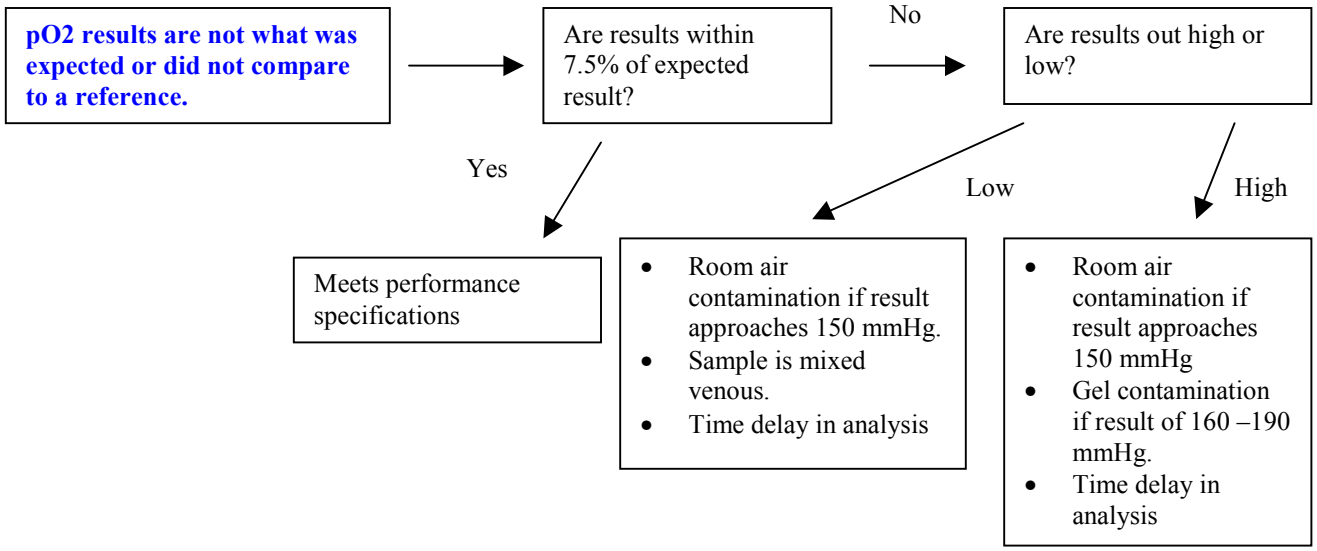

pO2 results out of range.
Confirm customer is using appropriate ranges for their QC lot and IRMA software version.
Confirm that the customer is using:
3cc or 1cc syringe
18-20 gauge needle
All users are using the same syringe size and needle size.
Injecting 1.5cc from a 3cc syringe or 0.8cc from a 1cc syringe.
All users are not removing air bubble from syringe prior to injection.
Using proper injection technique.
Equilibrated cartridges.
Are results out high or low?
High
Room Air contamination if expected pO2 result is less than 150 mmHg.
Room Temperature shift low.
Room Temperature not stable.
Gel contamination.
Low
Room Air contamination if expected pO2 result is greater than 150 mmHg.
Room Temperature shift High.

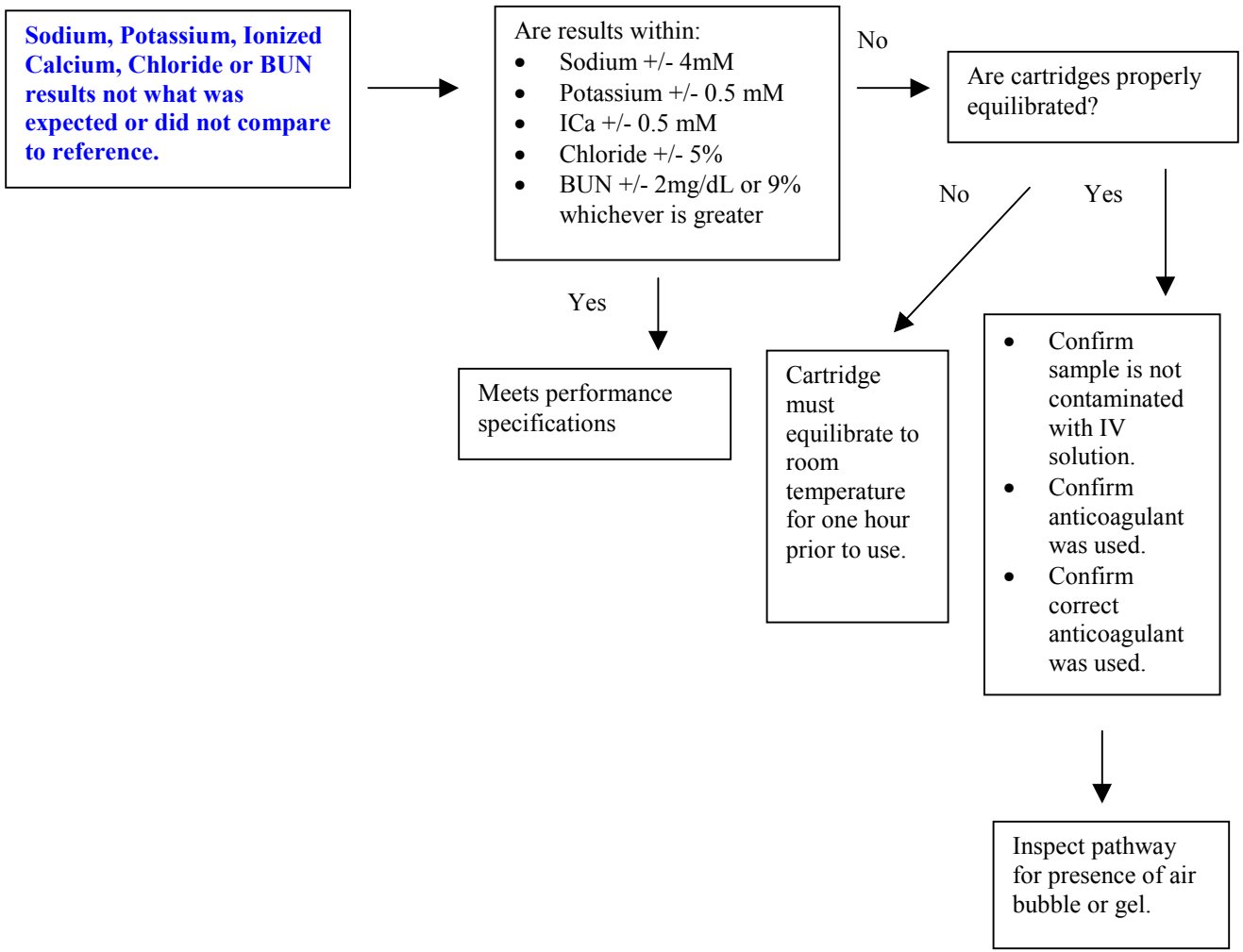

Sodium, potassium, ionized calcium results out of range.
Confirm customer is using appropriate ranges for their QC lot and IRMA software version.
Confirm that the customer is using:
3cc or 1cc syringe
18-20 gauge needle
All users are using the same syringe size and needle size.
Injecting 1.5cc from a 3cc syringe or 0.8cc from a 1cc syringe.
All users are not removing air bubble from syringe prior to injection.
Using proper injection technique.
Equilibrated cartridges.
Hematocrit results out of range.
Confirm customer is using appropriate ranges for their QC lot and IRMA software version.
Confirm that the customer is using:
3cc or 1cc syringe
18-20 gauge needle
All users are using the same syringe size and needle size.
Injecting 1.5cc from a 3cc syringe or 0.8cc from a 1cc syringe.
All users are not removing air bubble from syringe prior to injection.
Using proper injection technique.
Equilibrated cartridges.
Are results out high or low?
High
Room air contamination.
Low
Gel contamination

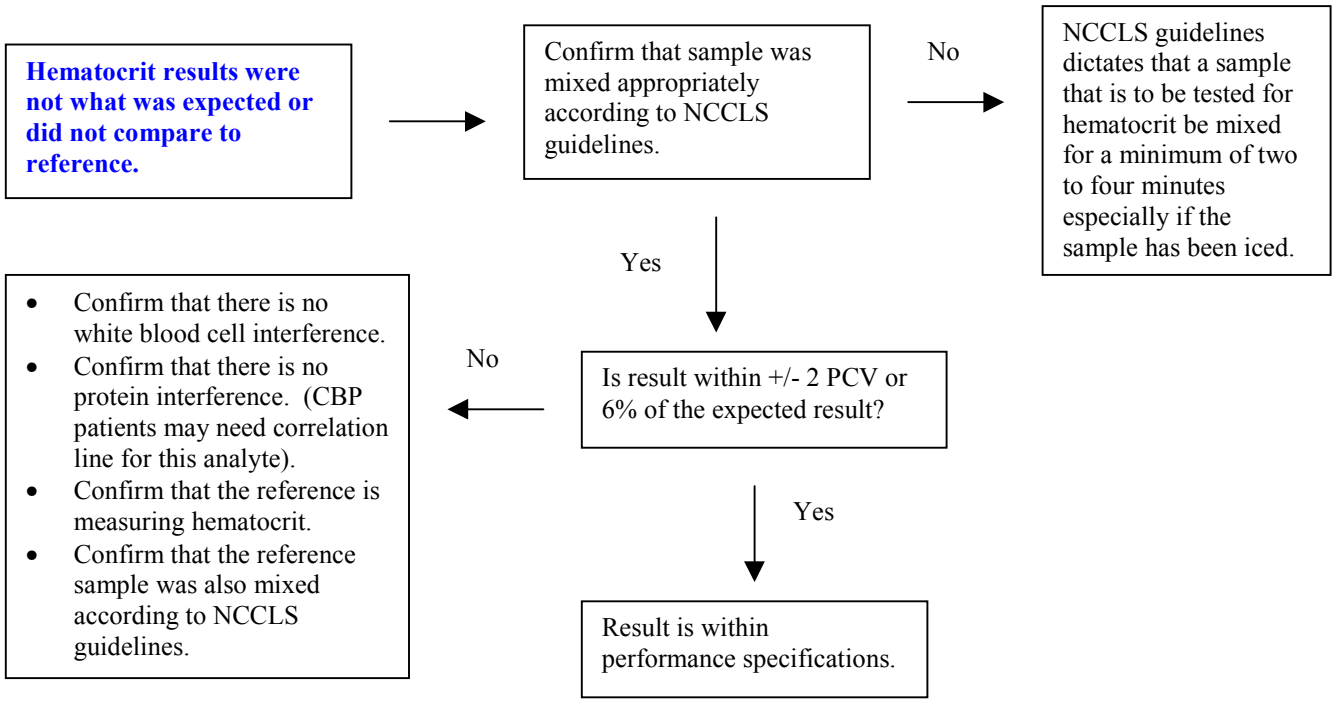
WHOLE BLOOD RESULTS:




pCO2 results are not what was expected or did not compare to a reference.
Confirm cartridges are equilibrated.
Yes
Are results greater than 5 mmHg from the expected result?
No
Equilibrate cartridges in a stable environment for a minimum of 72 hours
Yes
No
Meets Performance Specifications.
Suspect :
Cartridges are not equilibrated.
Room Air Contamination if result approaches 0 mmHg.
Gel contamination if result approaches 40 mmHg.
Something wrong with reference analyzer.


pO2 results are not what was expected or did not compare to a reference.
Are results within 7.5% of expected result?
No
Are results out high or low?
Yes
Low
High
Meets performance specifications
Room air contamination if result approaches 150 mmHg.
Sample is mixed venous.
Time delay in analysis
Room air contamination if result approaches 150 mmHg
Gel contamination if result of 160 –190 mmHg.
Time delay in analysis


Sodium, Potassium, Ionized Calcium, Chloride or BUN results not what was expected or did not compare to reference.
Are results within:
Sodium +/- 4mM
Potassium +/- 0.5 mM
ICa +/- 0.5 mM
Chloride +/- 5%
BUN +/- 2mg/dL or 9% whichever is greater
No
Are cartridges properly equilibrated?
No
Yes
Yes
Meets performance specifications
Cartridge must equilibrate to room temperature for one hour prior to use.
Confirm sample is not contaminated with IV solution.
Confirm anticoagulant was used.
Confirm correct anticoagulant was used.
Inspect pathway for presence of air bubble or gel.


Hematocrit results were not what was expected or did not compare to reference.
Confirm that sample was mixed appropriately according to NCCLS guidelines.
No
NCCLS guidelines dictates that a sample that is to be tested for hematocrit be mixed for a minimum of two to four minutes especially if the sample has been iced.
Yes
Is result within +/- 2 PCV or 6% of the expected result?
No
Confirm that there is no white blood cell interference.
Confirm that there is no protein interference. (CBP patients may need correlation line for this analyte).
Confirm that the reference is measuring hematocrit.
Confirm that the reference sample was also mixed according to NCCLS guidelines.
Yes
Result is within performance specifications.

IDMS

Corrupted Database →

- Double Click on **My Computer > (C:)** or the drive where IDMS is stored > **IDMS.** Then single click on **IDMS.MDB**
- From **File** on the toolbar, cursor down and click on **Rename.** Change the name to **IDMSBAD.MDB.**
- Login to IDMS.

Loss of Data →

- Double Click on **My Computer > (C:)** or the drive where IDMS is stored > **IDMS.** Then single click on **IDMS.MDB**
- From **File** on the toolbar, cursor down and click on **Rename.** Change the name to **IDMSBAD.MDB.**
- Login to IDMS.
- Resend from IRMA.

Runtime Errors and General Protection Faults →

- Reboot computer.
- Database will probably be corrupted.
- Double Click on **My Computer > (C:)** or the drive where IDMS is stored > **IDMS.** Then single click on **IDMS.MDB**
- From **File** on the toolbar, cursor down and click on **Rename.** Change the name to **IDMSBAD.MDB.**
- Login to IDMS.

If necessary refer to the IDMS troubleshooting guide for further help

IRMA SOFTWARE

Upgrade failure →

- Reboot computer
- Go through the steps with the customer
- Send new disks
- Request they use a different computer.

LIFESCAN

Modem failure →

Request that the customer performs the following check:

- From the **Main Menu**, press **Recall**
- Press **Status**
- Press **About**
- Look to see if the LFS SN line is filled in. If it is, IRMA and the module are communicating and this is not a failure. If the line is blank, no communication is occurring and module should be returned to Diametrics.

APPENDIX A: Aqueous Quality Control

Introduction & Intended Use
With the IRMA SL Blood Analysis System, Quality Control can be performed through two methods: electronic and aqueous controls.
It is important to follow the control manufacturer's recommended procedures for storage and equilibration of the control material prior to analysis on the IRMA SL.

Instructions for Use:
Equilibrate ampules at room temperature (18-25°C) for at least 4 hours before use.

1. Hold the ampule by its tip and shake it vigorously for 10 seconds.
2. Tap the liquid back into the base of the ampule. Sampling must take place within 2 minutes of opening the ampule.
3. Enter User ID (optional) at the display prompt on the IRMA SL Analyzer.
4. Initiate the Quality Control Test Sequence.
5. Open the foil pouch and remove the cartridge.
6. Remove the protective tape from the cartridge.
7. Insert the cartridge into the analyzer.
8. Verify cartridge type inserted (if necessary).
9. Verify or enter the cartridge information at the display prompt.
10. Select the control from the list of established controls.
11. After calibration is complete, carefully snap open the control ampule.
    To avoid cuts, protect your fingers with tissue or gloves, or use an ampule breaker.
12. Slowly draw the control sample into a 1 mL or 3 mL syringe using an 18-20 gauge needle or dispense tip.
13. Do not attempt to invert the syringe or expel bubbles from the syringe after drawing up the control solution.
14. Remove the needle, remove the cartridge cap, and inject the control into the cartridge. Use a minimum of 0.8 mL of the control sample in a 1.0 mL syringe or a minimum of 1.5 mL of the control sample in a 3.0 mL syringe.
15. Press "test" to initiate the analysis.

Use the expected values for each parameter as a guide in evaluating performance. Since performance is subject to sample temperature, Diametrics Medical recommends that each institution establish its own expected values and acceptable limits. The mean values established at your institution should fall within the expected ranges.

APPENDIX B: How to Establish a QC Range

The following method for establishing tentative QC ranges is recommended for the IRMA SL Blood Analysis System.

Test Method:

1. Testing should be conducted by multiple users to address any sample handling variations between different operators (i.e. falsely warming up the sample while shaking the ampule or analyzing a sample that was opened too long before analysis).

2. The initial analysis should be performed at the site where daily quality control testing will be performed in the future, such as a designated area at the POINT OF CARE (POC). This should minimize the effects of temperature variation on aqueous control material. The user may find it helpful to record daily room temperatures to determine temperature variation in the area where testing is conducted and control materials are stored.

3. Quality control materials should be stored at the testing site.

4. Testing should be conducted over a MINIMUM of a 5-day period to take into account any variations in room temperature, barometric pressure, and operator technique.

5. During this 5-day period, at least 20 samples for each level of control should be analyzed.

Handling the data:

1. Determine the MEAN (X) for each control parameter (pH, pCO2, pO2) for each control level.

$$X = \frac{\sum xi}{N}$$

2. Determine the standard deviation (s) value from the MEAN calculated in #1.

$$s = \sqrt{\frac{\sum (X - xi)^2}{N - 1}}$$

3. Eliminate any values that fall outside of ±3 SD of the mean (these results may be due to poor sample handling, etc.).

4. Recalculate the MEAN with the remaining values.

5. Recalculate the standard deviation.

By definition:

Approximately 68% of all determinations should fall within ±1 standard deviation of the mean value.

Approximately 95% of all determinations should fall within ±2 standard deviations of the mean value.

Approximately 99.7% of all determinations should fall within ±3 standard deviations of the mean value.

Laboratories commonly set control limits at either two or three standard deviations. If two standard deviations are chosen, the laboratory can predict that under these conditions, only one out of 20 determinations will exceed the limits because of chance. If a second result exceeds two standard deviations, it is then suspect of not meeting the conditions originally used in determining the mean. If a result exceeds three standard deviations, this result is genuinely suspect since this could occur by chance only three times in one thousand.

6. Assign tentative range based on the following:

Range Limits:	
pH	**Mean ± 0.03 for all 3 levels**
pCO2 (mmHg)	**Mean ± 8 for level 1; Mean ± 5 for levels 2 and 3**
pO2 (mmHg)	**Mean ± 10 for all 3 levels.**
Na^+ (mM)	**Mean ± 5 for all 3 levels.**
K^+ (mM)	**Mean ± 0.5 for all 3 levels.**
iCa^{++} (mM)	**Mean ± 0.1 for all 3 levels (units in mM)**
Hct (%Pcv)	**Mean ± 3%**
Cl- (mM)	**Mean ± 5 for all 3 levels**
BUN (mg/dL)	**Mean ± 6 for level 1; ± 5 for level 2; ± 3 for level 3**

or

7. Follow the normal protocol for your facility for handling data.

* **Due to the small number of observations, initial Quality Control limits should be established using the range limits above. Once the facility has approximately 100 points, the plus or minus 2 to 3 standard deviation limits may be used.**

** Data should be reviewed monthly after the range is established to verify that the range is still representative of conditions originally used in determining the mean.

Acceptance and rejection criteria for daily quality control:

* These are only suggestions. As a user, you may choose to follow the normal protocol established by your facility for the acceptance or rejection of daily quality control values.

1. If values are within range, the system is ready for patient testing.

2. If a value is outside of range, do the following:
   a) Have user check for the following:
      - Verify QC lot being tested is the same as the one for which the range is established.
      - Verify that sample integrity is acceptable i.e. no air bubbles in flow path or that opened sample has not been exposed to room air for longer than necessary.

   *** Be sure to record any observations or actions taken in action log.**

   b) Have the same operator repeat testing with another ampule of control. This will help determine whether sample handling by an individual operator is a possible source of error.
      - If repeat is within range, the system is ready for patient testing. Be sure to record any actions taken in action log .

   c) If value is still outside of range, have a different operator repeat analysis with different ampule.
      - If repeat is within range, the system is ready for patient testing. Be sure to record any actions taken in action log.

   d) If still out, determine if the room temperature of testing area has shifted significantly (for every 1°C change in temperature, a 1% change in gas value will be seen). Record any observations or actions taken in action log.

   e) If still having problems, contact Diametrics technical support at 1-800-949-4762.

3. If the value is just outside of range, follow the established protocol for your facility. This may be to accept the value and allow patient testing to continue while the next quality control results are monitored.

APPENDIX C: Electronic Quality Control

Diametrics Medical, Inc. manufactures the IRMA SL Blood Analysis System. This point of care instrument analyzes blood gases, sodium, potassium, ionized calcium and hematocrit and employs the use of Electronic Quality Control (EQC) as a way of assessing and documenting the accuracy and precision of the system.

Electronic Quality Control: Quality control is performed through a comprehensive diagnostic check of the edge connector, internal electronics, and analyte circuitry. An EQC test simulates the electronic signals that are produced by IRMA sensors during a cartridge test. Signals corresponding to both low and high analyte concentrations are tested, and results must fall within strict predetermined thresholds for the test to pass. IRMA EQC is an internal method, and does not require the use of an external EQC card.

Temperature Test: The IRMA temperature control system is tested at 37°C using the IRMA temperature card.

Diametrics Quality Control Recommendation: Following method verification and establishment of aqueous quality control limits, Diametrics Medical, Inc. (DMI) recommends EQC as the primary method of assessing system accuracy and precision. Since each test site may have unique requirements, each site should select and verify a quality control system that meets their needs. DMI recommends the quality control be performed as follows:

Run an EQC test:
- Once per shift of patient testing on each analyzer;
- When the analyzer experiences a significant change in storage temperature ie: movement from a cold to a hot, or hot to a cold environment.
- Whenever the performance of the analyzer requires verification, according to facility or regulatory agency protocol.

Run two levels of Aqueous Control:
- Before a new cartridge lot or shipment is put into use, (following the required equilibration period) to verify proper shipping and equilibration conditions. Cartridge lot verification is not required for each analyzer in use.

Additional Aqueous Control testing:
- Is required only if cartridges are required to go through an additional equilibration period due to temperature fluctuations of greater than 8°C in the cartridge storage area.
- If the cartridges are required to go through an additional equilibration period, run two levels of aqueous control before putting the cartridge lot back into use.

Run a Temperature Test:
- Monthly to verify that the IRMA temperature control system is operating properly.

The electronic checks span the measurement range of the device for each analyte. In order to assess accuracy acceptability, performance is checked at three distinct points for each analyte.

Edge Connector: IRMA relies on consistent connections between the instrument and the cartridge. These connections are made through the edge connector. Once the EQC test is initiated, all connection pins are tested individually to assure contact.

Internal Electronics: Any contamination between sensor circuits can cause erroneous results. During the Electronic Quality Control test, leakage current is checked in the sensor circuitry. Leakage current is unwanted current that flows through a circuit because of an unwanted short. This circuit is used throughout the system to measure any possible leakage current.

Analyte Circuitry: Our system includes three basic types of sensor circuits; ampometric, potentiometric and conductometric. Each type of sensor operates over a fixed range of sensor responses. These responses must be measured within certain specifications throughout that range in order to give consistent results.

Temperature Control System: IRMA's temperature control system maintains a sample at body temperature during a blood gas test. The temperature controller uses input from the infrared probe to turn the heater on and off to control sample temperature. The heater is located on the cartridge. IRMA's Temperature Test checks this system with the card being heated and controlled exactly as a blood gas cartridge would be. The temperature is measured in the Temperature card and compared with expected results. (37°C ± 0.6°C)

APPENDIX D: Syringe Information

Incompatible ABG Syringes

In general, there are three primary types of ABG syringes that are incompatible with the IRMA system:

1. Frictionless ("pulsating") syringes – after sample injection, the hub of the syringe will continue to travel downwards by itself, until all the sample has flowed into the cartridge. The analyzer is unable to heat the sample adequately as it slowly continues to move through the sample path, and the test results in a sensor error. The following are examples of frictionless syringes that are incompatible with the IRMA system without the use of a check valve:

- Concord Pulsator Arterial Blood Sampling Kit
- Bard Parker Liquihep Kit
- Bard Parker Dri-Hep 3cc (looks like 5cc but only holds 3cc)

2. Syringes that contain a mixing ball, or non-dissolving disk impregnated with heparin. Due to the vertical orientation of the syringe during injection, the ball or disk may become lodged in the bottom of the syringe, and the sample may hemolyze when it is forced through or around the plug during injection. The following syringe is incompatible with the IRMA system:

- Radiometer QS 50 Arterial Blood Sampler

3. Incompatible Hub

- The Bard Parker Safety Lock syringe has a large hub that does not fit into the luer port of the IRMA cartridge.

The compatibility of a syringe that is not listed can be determined by evaluating it in terms of the aforementioned characteristics. Please forward any syringes that you would like to have formally evaluated to Diametrics Technical Support.

APPENDIX E: Internal EQC Error Codes

Internal EQC Test Description

Test Type	Error Codes	Description of Test	POSSIBLE CAUSE
General Status	101001	Checks IRMA instrument internal temperature.	• The environment in which Irma is operating in is too hot (>40 C) or too cold (< 12C). • IRMA was recently (within the past hour) moved from an environment that is extremely low or high temperature. • Broken temp measurement circuit
General Status	101002	Checks power into main PCB: Input voltage too high. Above 10V.	• AC Adapter Failure • Broken measurement circuit.
Noise	106001-106014	Checks if there is excessive noise on non-sensor data channels. (Noise on sensor channels is measured during tests and uses different methods for filtering.)	• 5 Volt Regulator Failure • Electromagnetic Interference (EMI) • Latent circuit failure
Leakage	108001	Checks for null leakage on MEMB channel without generating a stimulus leakage current on other pins. (this channel is not currently used for anything, but maybe someday)	• Extremely high humidity • Contamination on MEMB channel on main circuit board • Latent circuit failure
Leakage	108002	Checks for null leakage on ILEAK channel without generating a stimulus leakage current on other pins. This is the circuit we use for a lot of the leakage testing.	• Extremely high humidity • Contamination on ILEAK channel on main circuit board • Latent circuit failure
Leakage	108003	Checks for null leakage on ISE1 channel without generating a stimulus leakage current on other pins.	• Extremely high humidity • Contamination on ISE1 channel on main circuit board • Latent circuit failure
Leakage	108004	Checks leakage between ISE1 and other pins. (not WKG1-3 or Heater Low)	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108005	Checks for null leakage on ISE2 channel without generating a stimulus leakage current on other pins.	• Extremely high humidity • Contamination on ISE2 channel on main circuit board • Latent circuit failure
Leakage	108006	Checks leakage between ISE2 and other pins. (not WKG1-3 or Heater Low)	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108007	Checks for null leakage on ISE3 channel without generating a stimulus leakage current on other pins.	• Extremely high humidity • Contamination on ISE3 channel on main circuit board • Latent circuit failure

Test Type	Error Codes	Description of Test	POSSIBLE CAUSE
Leakage	108008 - 108009	Checks leakage between ISE3 and other pins. (not WKG1-3 or Heater Low)	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108010	Checks for null leakage on ISE4 channel without generating a stimulus leakage current on other pins.	• Extremely high humidity • Contamination on ISE4 channel on main circuit board • Latent circuit failure
Leakage	1080011 – 108013	Checks leakage between ISE4 and other pins. (not WKG1-3 or Heater Low)	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108014	Checks for null leakage on ISE5 channel without generating a stimulus leakage current on other pins.	• Extremely high humidity • Contamination on ISE5 channel on main circuit board • Latent circuit failure
Leakage	108015 - 108018	Checks leakage between ISE5 and other pins. (not WKG1-3 or Heater Low)	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108019	Checks for null leakage on ISE6 channel without generating a stimulus leakage current on other pins.	• Extremely high humidity • Contamination on ISE6 channel on main circuit board • Latent circuit failure
Leakage	108020 - 108024	Checks leakage between ISE6 and other pins. (not WKG1-3 or Heater Low)	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108025	Checks for null leakage on ISEREF channel without generating a stimulus leakage current on other pins.	• Extremely high humidity • Contamination on ISEREF channel on main circuit board • Latent circuit failure
Leakage	108026 - 108031	Checks leakage between ISEREF and other pins. (not WKG1-3 or Heater Low)	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108032	Establishes and checks a reference value on ISE1 to be used for comparison on next 4 tests.	• Extremely high humidity • Contamination on ISE1 channel on main circuit board • Latent circuit failure
Leakage	108033 - 108036	Checks leakage between ISE1 and WKG1-3 and Heater Low	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure

Test Type	Error Codes	Description of Test	POSSIBLE CAUSE
Leakage	108037	Establishes and checks a reference value on ISE2 to be used for comparison on next 4 tests.	• Extremely high humidity • Contamination on ISE2 channel on main circuit board • Latent circuit failure
Leakage	108038 - 108041	Checks leakage between ISE2 and WKG1-3 and Heater Low	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108042	Establishes and checks a reference value on ISE3 to be used for comparison on next 4 tests.	• Extremely high humidity • Contamination on ISE3 channel on main circuit board • Latent circuit failure
Leakage	108043 - 108046	Checks leakage between ISE3 and WKG1-3 and Heater Low	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108047	Establishes and checks a reference value on ISE4 to be used for comparison on next 4 tests.	• Extremely high humidity • Contamination on ISE4 channel on main circuit board • Latent circuit failure
Leakage	108048 - 108051	Checks leakage between ISE4 and WKG1-3 and Heater Low	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108052	Establishes and checks a reference value on ISE5 to be used for comparison on next 4 tests.	• Extremely high humidity • Contamination on ISE5 channel on main circuit board • Latent circuit failure
Leakage	108053 - 108056	Checks leakage between ISE5 and WKG1-3 and Heater Low	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108057	Establishes and checks a reference value on ISE6 to be used for comparison on next 4 tests.	• Extremely high humidity • Contamination on ISE6 channel on main circuit board • Latent circuit failure
Leakage	108058 - 108061	Checks leakage between ISE6 and WKG1-3 and Heater Low	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108062	Establishes and checks a reference value on ISEREF to be used for comparison on next 4 tests.	• Extremely high humidity • Contamination on ISEREF channel on main circuit board • Latent circuit failure

Test Type	Error Codes	Description of Test	POSSIBLE CAUSE
Leakage	108063 - 108066	Checks leakage between ISEREF and WKG1-3 and Heater Low	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108067	Checks for null leakage on WKG1 channel without generating a stimulus leakage current on other pins.	• Extremely high humidity • Contamination on WKG1 channel on main circuit board • Latent circuit failure
Leakage	108068 - 108069	Checks leakage between WKG1 and other pins.	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108070	Checks for null leakage on WKG2 channel without generating a stimulus leakage current on other pins.	• Extremely high humidity • Contamination on WKG2 channel on main circuit board • Latent circuit failure
Leakage	108071	Checks leakage between WKG2 and other pins.	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108072	Checks for null leakage on WKG3 channel without generating a stimulus leakage current on other pins.	• Extremely high humidity • Contamination on WKG3 channel on main circuit board • Latent circuit failure
Leakage	108073	Checks leakage between WKG3 and other pins.	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108074	Checks leakage from MF1 (multifunction 1) pin to other MF pins, reference pins, heater hi and heater low.	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108075	Checks leakage from MF2 (multifunction 2) pin to other MF pins, reference pins, heater hi and heater low.	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
Leakage	108076	Checks leakage from MF3 (multifunction 3) pin to other MF pins, reference pins, heater hi and heater low.	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure

Test Type	Error Codes	Description of Test	POSSIBLE CAUSE
Leakage	108077	Checks leakage from MF4 (multifunction 1) pin to reference pins and heater low.	• Contaminated Edge Connector • Extremely high humidity • Contamination between channels on main circuit board • Latent circuit failure
ISEREF	109001 - 109005	Checks the ISEREF circuit by introducing 5 voltages across its operating range.	• Contaminated Edge Connector • Extremely high humidity • Latent circuit failure
General Status	110001	Checks VREF voltage. This is the reference voltage we use for our analog to digital conversion of sensor channel data. It needs to be stable.	• Extremely high humidity • Latent circuit failure
ISE1-6 WKG1 Function	110002 - 110029	Applies 5 different potentials independently to all 6 ISE channels and 5 different current levels for WKG1. This stimulus verifies the function of these channels over their entire range. We use this as a screening check to make sure the channels are working pretty good. Phase 18 checks these channels more thoroughly.	• Contaminated Edge Connector • Extremely high humidity • Latent circuit failure
WKG1 Function	110030	Check the input switch into WKG1 circuit. (large current)	• Latent circuit failure
ISE1-6 WKG1 Function	110031 - 110066	Apply 5 different voltages to all 6 ISE channels (current for WKG1). This stimulus is over a relatively small signal range. We will use this data for phase 18 comparison tests.	• Contaminated Edge Connector • Extremely high humidity • Latent circuit failure
WKG1 Function	110067	Check the input switch into WKG1 circuit. (small current)	• Latent circuit failure
General Status	110068	Check a circuit called I_MON. This circuit is not used now, but may be someday.	• Latent circuit failure
WKG2-3 Function	111001 - 111012	Check WKG2-3 for proper operation by providing stimulus current to each. Three ranges are applied. The input switches to these circuits are also checked.	• Extremely high humidity • Latent circuit failure
MF1-4 Bias Function	112001- 112022	Each bias circuit is individually checked to assure they can set the bias to the correct voltage and source current. In addition, any associated switches are tested.	• Latent circuit failure
AC Signal Function	113001- 113012	The circuit used to generate the AC signal is tested to assure the correct frequency is used during hematocrit measurements	• Latent circuit failure
HCT Circuit Function	115001- 115024	The instrument's open circuit impedance is checked on all channels to assure it has not changed since calibration.	• Contaminated Edge Connector • Extremely high humidity • Latent circuit failure
HCT Circuit Function	116001- 116048	The resistance measurement circuit is checked on all hematocrit channels by measuring a known resistor or "zero" point. Results are checked to assure they have not changed since calibration.	• Contaminated Edge Connector • Extremely high humidity • Latent circuit failure

Test Type	Error Codes	Description of Test	POSSIBLE CAUSE
ISE1-6 WKG1 Drift	117001 - 117015	Check for drift on ISE1-6 and WKG1 channels. We apply a reference voltage/current to the channels and measure them. We then wait for about 30 seconds (meanwhile we check other circuits) then check them again to make sure they have not drifted. Tests 1-7 are the initial checks, tests 8-15 are the final checks.	• Contaminated Edge Connector • Extremely high humidity • Latent circuit failure
ISE1-6 WKG1 Function	118001 - 118030	Compare each ISE channel against another ISE channel. Also check ISE1 against WKG1. These checks use data collected in phase 10 to verify that the ISE1-6 and WKG1 channels have the precision required for quality sensor data measurement.	• Contaminated Edge Connector • Extremely high humidity • Latent circuit failure
ISE1-6 WKG1 Function	118031 - 118050	Use data generated from the first half of phase 18 to perform differential comparisons of the ISE1-6 channels. This is identical to a sensor measurement where we perform a differential measurement between calibrant and blood. This is the most precise testing we perform on the ISE channels.	• Contaminated Edge Connector • Extremely high humidity • Latent circuit failure

Description of Possible Causes:

- **Contaminated Edge Connector** – All edge connectors are tested to rigorous specifications at 80%RH before they are used for new product or replacement. (this testing was implemented in spring '98) It is likely, unlike a high humidity issue, that once an edge connector is contaminated, it cannot be recovered. The most likely contaminants are aqueous fluid and blood, but may also include plastic shavings from many (thousands) of cartridge insertions. There is a chance that contamination could get onto the main board as well as the edge connector The most likely errors will occur in phase 8 if contamination has occurred.
- **Extremely High Humidity** – This should be understood as more than 80% relative humidity. IRMA can withstand higher humidity, but it should not be expected to perform ideally until it has had a chance to dry out. A special condition may occur besides high humidity that is worth discussing. Particularly, users may not understand that even though they may be in a dry environment, large, quick changes in temperature (from cold to hot) will cause condensation on both the inside and outside of IRMA. Condensation is particularly tough to solve. Since air transfer occurs very slowly from inside to outside of IRMA, it takes a long time to get the moisture out of IRMA. The best solution is to turn IRMA on for several hours to aid in the drying out process. An EQC error due to humidity should always "fix" itself given a lower humidity environment (high humidity most likely will not cause permanent damage to IRMA). If the user has allowed plenty of drying time in less humid conditions and the EQC errors continue, it is likely the errors are not due to high humidity. Although high humidity could be the cause of failure for most phases, phase 8 will likely be the first to indicate the RH is too high.
- **Contamination between Channels on Main PCB** – This will most likely be due to contamination that was on the main board from the manufacturing process. Often, contamination from assembly of the board requires an "activation" means. This could be simply the passage of time. Slight contamination can become conductive over time. It would more likely be a combination of extended higher humidity and time. Many contaminants are benign until moisture is added to the mix. As a result, it may appear as though an extremely high humidity situation has occurred, phase 8 errors, but the problem is more impervious to the normal drying out solution discussed in the High Humidity section.

NOTE REGARDING LEAKAGE FAILURES: Leakage current is additive. In other words, one failure mode alone may not cause the error to occur. Sometimes it is the combination of contamination and high humidity that causes a failure to occur.

- **Latent Circuit Failure** - The circuit under test worked well at one time. For some reason, it no longer functions the same. This could be due to many reasons. Mechanical failure such as a broken solder joint may result from dropping or banging. There is a possibility that ESD damage may occur while an edge connector is being changed since the ESD protection is in the edge connector and without it damage to the main PCB is possible.

Internal EQC does not check:

- Cartridge Failures
- Barometric Pressure Measurement
- Battery or AC Adapter Failures (except where noted)
- Any failure that prevents power on
- Heater control circuit
- Continuity through edge connector

APPENDIX F: Temperature Test Error Codes

Temperature Control Test Description

Test Type	Error Codes	General Description of Test	Possible Causes
Continuity	101101- 101110	These checks determine whether some of the Temp card pins are connected to the analyzer. Each discrete check actually checks 2 pins. The pins checked are: REF1-3 ISE1-6 WKG1-3 ISEREF	• Broken Edge Connector Pin • Broken Edge Connector Flex Circuit • Broken Temp card • Contamination in edge connector raising impedance • Note: IRMA relies upon certain pins being intact in order to recognize that the card has been inserted and in order to identify the card. Because of this, a broken Temp card may not be detected or properly identified and therefore the test will not proceed.
General Status	101111	Check initial card temperature	• The environment in which Temp Card is stored in is too hot (>40 C) or too cold (< 12C). • The environment in which the system is operating in is too hot (>40 C) or too cold (< 12C). • Broken temp measurement circuit.
General Status	101112	Checks IRMA instrument internal temperature.	• The environment in which Irma is operating in is too hot (>40 C) or too cold (< 12C). • IRMA was recently (within the past hour) moved from an environment that is extremely low or high temperature. • Broken temp measurement circuit
General Status	101113	Checks power into main PCB: Input voltage too high. Above 10V.	• AC Adapter Failure • Broken measurement circuit.
Continuity	103101 - 103109	These checks determine whether some of the Temp card pins are connected to the analyzer. We don't just check for connection, but for a certain maximum allowed impedance.Each discrete check actually checks 2 pins. We use the impedance (Hct) measurement circuit for these checks. The pins checked are: MF1-4 Heater High Heater Low	• Broken Edge Connector Pin • Broken Edge Connector Flex Circuit • Broken Temp card • Contamination in edge connector raising impedance • AC Generator Circuit Failure • Impedance Measurement Circuit Failure • Note: If either the Heater High or the Heater Low pins are completely open, the card will not even be recognized as inserted.
Temp Control Data	105101- 105103	The heater is the same as on any cartridge, but a thermistor is located in place of the sensors. The Temp Card is heated and controlled exactly as any cartridge The temperatureis measured via the thermistor and compared with expected results. These tests collect preliminary data for the final thermistor check.	• IR Probe Blocked or dirty. • Temp Card not fully inserted • IR Probe Misaligned due to shock • Temp card damaged such that theIR probe window on back blocked or the thermistor is disconnected. • Latent IR probe circuit damage

Test Type	Error Codes	General Description of Test	Possible Causes
Temp Control Result	109101	Most often, this will be the only temperature failure test even though all the phase 5 tests pass. This check takes the phase 5 data and the calibration code and calculates the final temperature result. There is only one error for the temperature check indicating that the temperature is outside the 36 to 38 degree C range. The control temperature of the last "passed" Temperature Test can be seen by going to the **About** screen. "Passing TT" means passing temperature test. A 4-digit number represents the xx.xx degrees C. Also listed is the date and time the that last passing temperature test occurred.	• IR Probe Blocked or dirty. • Temp Card not fully inserted • IR Probe Misaligned due to shock • Temp card damaged such that theIR probe window on back blocked or the thermistor is disconnected. • Latent IR probe circuit damage. • Incorrect Calibration Code Entered.
Temp Control Result	10XXXX (Last Error Code Only)	In the Temperature Test Errors section, the final code for any test is the control temperature. The code is decoded as follows: e.g. 103556 is read as 35.56 degrees C.	• See 109101 if this value is <103600 or >103800.

Temperature Control Test does not check:

- Cartridge Failures
- Barometric Pressure Measurement
- Battery or AC Adapter Failures (except where noted).
- Failures that prevent detection of inserted card
- Any failure that prevents power on.
- IRMA Analyzer functions checked in the Internal EQC test.

APPENDIX G: Usage Log Error Codes

Usage Log

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
1003	INSTRUMENT TEMP OUT HIGH	• The environment in which IRMA is operating in is too hot (>40 °C) • Faulty IR probe which requires replacement
1004	INSTRUMENT TEMP OUT LOW	• The environment in which IRMA is operating in is too cold (>12 °C) • Faulty IR probe which requires replacement
1005	IR PROBE TEMP (CARD) OUT HIGH	• Customer is re-inserting a cartridge that was in the analyzer and therefore was already heated above the acceptable limit • The cartridge storage environment is greater than 30 °C • Faulty IR probe which requires replacement
1006	IR PROBE TEMP (CARD) OUT LOW	• The cartridge storage environment is less than 12 °C • Faulty IR probe which requires replacement
2001	CARD REMOVED PREMATURELY	• Cartridge removed prematurely -- User error, repeat in- service
2002	INJECTION NOT DONE IN TIME	• Test button not pressed in time -- User error, repeat in-service
2003	TEST DATA NOT ENTERED IN TIME	• All test data not entered in time -- User error, repeat in service
2004	CAL INJECT NOT DONE IN TIME	• Time to deploy cap expired -- User error, repeat in-service
2006	TEST BUTTON PRESSED TOO LATE	• Time from injection to test button push too long -- User error, repeat in-service
2007	NO INJECTION PERFORMED	• Injection not performed and test button pushed -- User error, repeat in-service
2100	CARD ID OBTAINING DIFF VALUES	• Wet or contaminated Edge Connector, clean and dry or replace • Malfunctioning cartridge • Invalid cartridge type for software installed in the IRMA. Verify compatability.
3001	BATTERY IS LOW ON POWER	• Low Battery. This is more of an indicator than an error.
3201	AC POWER ADAPTER VOLTAGE HI	• AC Adapter is not functioning properly, output voltage is too high for IRMA, replace AC Adapter
5002	IR TEMP OVERSHOT SETPOINT	• Faulty IR probe which requires replacement
5003	IR CAL TIMEOUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Dirty IR probe. Clean and dry the probe. • Obstructed or recessed IR probe. Verify probe is flush with the surface. • Instrument not equilibrated to new environment (30 minutes is required) • Faulty IR probe which requires replacement
5004	IR SAMPLE TIMEOUT	• Wet or dirty IR probe. Clean and dry the probe. • Obstructed or recessed IR probe. Verify probe is flush with the surface. • Faulty IR probe which requires replacement

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
5006	IR TEMP OUT OF SPEC DURING SAMPLE	• Wet or dirty IR probe. Clean and dry the probe. • Obstructed or recessed IR probe. Verify probe is flush with the surface. • Faulty IR probe which requires replacement
5007	pH CAL TIMEOUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Malfunctioning cartridge
5008	pH SAMPLE TIMEOUT	• Problem with Sample • Malfunctioning cartridge
5009	CO2 CAL TIMEOUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Malfunctioning cartridge
5010	CO2 SAMPLE TIMEOUT	• Problem with Sample • Malfunctioning cartridge
5011	IR TEMP OUT OF SPEC DURING CAL	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Dirty IR probe. Clean and dry the probe. • Obstructed or recessed IR probe. Verify probe is flush with the surface. • Instrument not equilibrated to new environment (30 minutes is required) • Faulty IR probe which requires replacement
5012	O2 CAL IS ON RAIL	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Malfunctioning cartridge
5013	O2 CAL TIMEOUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Malfunctioning cartridge
5014	O2 SAMPLE TIMEOUT	• Problem with Sample • Malfunctioning cartridge
5015	Final O2 result is negative	• Problem with Sample • Malfunctioning cartridge
5016	Final O2 result greater than 1000 mm Hg/133.3 kPa	• Problem with Sample • Malfunctioning cartridge
5017	Final CO2 result is negative	• Problem with Sample • Cartridges not equilibrated • Malfunctioning cartridge
5018	Final CO2 result is greater than 200 mm Hg/26.7 kPa	• Problem with Sample • Hole in cartridge foil pouch • Cartridges not equilibrated

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
		• Malfunctioning cartridge
5019	pH result is less than 6.0	• Problem with Sample • Cartridges not equilibrated • Malfunctioning cartridge
5020	pH result is greater than 8.0	• Problem with Sample • Cartridges not equilibrated • Malfunctioning cartridge
5022	FALSELY DETECTED CARD OUT--O2	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Malfunctioning cartridge
5023	FALSELY DETECTED CARD OUT--HCT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Malfunctioning cartridge
5024	pH NOT RESPONDING QUICKLY (CAL)	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5025	CO2 NOT RESPONDING QUICKLY (CAL)	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5026	PH SENSITIVITY FAILED CHECK #3	• Malfunctioning cartridge
5029	pH CORRECTION TOO LARGE	• Malfunctioning cartridge
5030	pH SENSITIVITY FAILED CHECK #1	• Malfunctioning cartridge
5031	pH SENSITIVITY FAILED CHECK #2	• Malfunctioning cartridge • Possible high cartridge storage temperature
5032	FALSELY DETECTED CARD OUT--TEMP	• Dirty IR probe. Clean and dry the probe. • Obstructed or recessed IR probe. Verify probe is flush with the surface. • Faulty IR probe which requires replacement
5034	K DRIFT AT INJECT OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5035	Na DRIFT AT INJECT OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
		or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5036	Na CAL TIMEOUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Malfunctioning cartridge
5037	Na SAMPLE TIMEOUT	• Problem with Sample • Malfunctioning cartridge
5038	Ca CAL TIMEOUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Malfunctioning cartridge
5039	Ca SAMPLE TIMEOUT	• Problem with Sample • Malfunctioning cartridge • EDTA anti-coagulant used on sample
5040	K CAL TIMEOUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Malfunctioning cartridge
5041	K SAMPLE TIMEOUT	• Problem with Sample • Malfunctioning cartridge
5042	K DELTA mV CHECK FAIL	• Problem with Sample • Malfunctioning cartridge
5043	K WARMUP FAIL	• Moisture on edge connector possibly caused by water droplets on the lead tape prior to removal. Dry edge connector or replace. Instruct customer on the potential cause of this error and ask them to dry the lead tape prior to removal if moisture is observed. • Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Malfunctioning cartridge
5045	Na NOT RESPONDING QUICKLY (CAL)	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5046	Ca NOT RESPONDING QUICKLY (CAL)	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace.

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
		• Malfunctioning cartridge
5047	K NOT RESPONDING QUICKLY (CAL)	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5048	K DRIFT CORRECTION OUT	• Problem with Sample • Malfunctioning cartridge
5049	Na DRIFT CORRECTION OUT	• Problem with Sample • Malfunctioning cartridge
5050	HCT PHASE 0 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5051	HCT PHASE 1 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5052	HCT PHASE 2 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5053	HCT PHASE 3 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
5054	HCT PHASE 4 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5055	HCT PHASE 5 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5056	HCT PHASE 6 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5057	HCT PHASE 7 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5058	HCT PHASE 8 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5059	HCT PHASE 9 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
		connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5060	HCT PHASE 10 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5061	HCT PHASE 11 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5062	HCT PHASE 12 DATA OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5064	CONDUCTANCE RATIOS NOT SIMILAR	• Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5065	CONDUCTANCE DRIFT TIMEOUT	• Wet or dirty IR probe. Clean and dry the probe. • Obstructed or recessed IR probe. Verify probe is flush with the surface. • Faulty IR probe which requires replacement • Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
		• Malfunctioning cartridge
5066	TEMP COEFFICIENT CHECK IS OUT LOW	• Wet or dirty IR probe. Clean and dry the probe. • Obstructed or recessed IR probe. Verify probe is flush with the surface. • Faulty IR probe which requires replacement • Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Malfunctioning cartridge
5067	TEMP COEFFICIENT CHECK IS OUT HIGH	• Wet or dirty IR probe. Clean and dry the probe. • Faulty IR probe which requires replacement • Malfunctioning cartridge
5070	Na INITIAL ROOM TEMP mV OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5071	Na CAL mV TOO LOW	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5072	Na CAL mV TOO HIGH	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5073	K INITIAL ROOM TEMP mV OUT	• Snap cap (on applicable products) deployed prematurely. • Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5074	K CAL mV TOO LOW	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace.

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
		• Malfunctioning cartridge
5075	K CAL mV TOO HIGH	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5080	CONDUCTANCE RATIO FAILURE #2	• Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Bubbles or voids in calibration medium • Bubbles, voids, gel fragments, or other problems with sample • Malfunctioning cartridge
5089	Final Na result less than 50	• Problem with Sample • Malfunctioning cartridge
5090	Final Na result greater than 250	• Problem with Sample • Malfunctioning cartridge
5091	Final K result less than 0.5	• Problem with Sample • Malfunctioning cartridge
5092	Final K result greater than 25.0	• Problem with Sample • Malfunctioning cartridge
5093	Final iCa result less than 0.2 mM/0.4 mEq/L/0.8 mg/dL	• EDTA used as an anticoagulant • Problem with Sample • Malfunctioning cartridge
5094	Final iCa result greater than 10 mM/20 mEq/L/40.08 mg/dL	• Problem with Sample • Malfunctioning cartridge
5095	Final Hct result is Negative	• Problem with Sample • Malfunctioning cartridge
5096	Final Hct result is greater than 80	• Problem with Sample • Malfunctioning cartridge
5097	ALL REQUIRED VALUES SUPPRESSED	• Problem with Sample • Malfunctioning cartridge
5098	Noisy 5 Volt Regulator	• 5V regulator failure
5099	Noisy 5 Volt Regulator	• 5V regulator failure
5101	BUN INTIAL ROOM TEMP mV OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
5102	BUN CAL mV TOO LOW	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5103	BUN CAL mV TOO HIGH	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5104	BUN DRIFT AT INJECT OUT	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5110	BUN SAMPLE TIMEOUT	• Problem with Sample • Malfunctioning cartridge
5120	BUN OUT OF RANGE LOW	• Problem with Sample • Malfunctioning cartridge
5121	BUN OUT OF RANGE HIGH	• Problem with Sample • Malfunctioning cartridge
5122	BUN RESULTS BAD	• Problem with Sample • Malfunctioning cartridge
5210	Cl DRIFT CORRECTION OUT	• Problem with Sample • Malfunctioning cartridge
5220	Cl OUT OF RANGE LOW	• Problem with Sample • Malfunctioning cartridge
5221	Cl OUT OF RANGE HIGH	• Problem with Sample • Malfunctioning cartridge
5301	GL CAL CHECK LOW	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5320	GL OUT OF RANGE LOW	• Problem with Sample • Malfunctioning cartridge
5321	GL OUT OF RANGE HIGH	• Problem with Sample

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
		• Malfunctioning cartridge
5322	O2 CR too low.	• Problem with Sample, possibly low or no oxygen. • Malfunctioning cartridge
5323	Sample Amp 1 Drift too negative.	• Problem with Sample • Malfunctioning cartridge
5324	Amp1 CR 2 and 3 Don't Match at Low Level	• Problem with Sample • Malfunctioning cartridge
5325	Amp1 CR 1 and 2 Don't Match at High Level	• Problem with Sample • Malfunctioning cartridge
5326	Amp1 CR 2 and 3 Don't Match	• Problem with Sample • Malfunctioning cartridge
5327	Amp1 Glucose out of Range High	• Problem with Sample • Malfunctioning cartridge
5328	Amp1 Glucose out of Range Low	• Problem with Sample • Malfunctioning cartridge
5329	Glucose Amp 1 Ratio Check #1	• Problem with Sample • Malfunctioning cartridge
5330	Glucose Amp 1 Ratio Check #2	• Problem with Sample • Malfunctioning cartridge
5331	Glucose Amp 1 Ratio Check #3	• Problem with Sample • Malfunctioning cartridge
5332	Glucose Amp 1 Ratio Check #4	• Problem with Sample • Malfunctioning cartridge
5333	Sample Amp 2 Drift too negative.	• Problem with Sample • Malfunctioning cartridge
5334	Amp2 CR 2 and 3 Don't Match at Low Level	• Problem with Sample • Malfunctioning cartridge
5335	Amp2 CR 1 and 2 Don't Match at High Level	• Problem with Sample • Malfunctioning cartridge
5336	Amp2 CR 2 and 3 Don't Match	• Problem with Sample • Malfunctioning cartridge
5337	Amp2 Glucose out of Range High	• Problem with Sample • Malfunctioning cartridge
5338	Amp2 Glucose out of Range Low	• Problem with Sample • Malfunctioning cartridge
5339	Glucose Amp 2 Ratio Check #1	• Problem with Sample

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
		• Malfunctioning cartridge
5340	Glucose Amp 2 Ratio Check #2	• Problem with Sample • Malfunctioning cartridge
5341	Glucose Amp 2 Ratio Check #3	• Problem with Sample • Malfunctioning cartridge
5342	Glucose Amp 2 Ratio Check #4	• Problem with Sample • Malfunctioning cartridge
5343	Glucose Amp 1 and Amp 2 results different.	• Problem with Sample • Malfunctioning cartridge
5344	Glucose Amp 1 4th cal value too high.	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5345	Glucose Amp 1 5th cal value too high.	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5346	Glucose Amp 1 6th cal value too high.	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5347	Glucose Amp 1 drift during calibration.	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5348	Glucose Amp 2 4th cal value too high.	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5349	Glucose Amp 2 5th cal value too high.	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
		connector or replace. • Malfunctioning cartridge
5350	Glucose Amp 2 6th cal value too high.	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
5351	Glucose Amp 2 drift during calibration.	• Incomplete cartridge connection to edge connector. Possible cartridge lead problem or edge connector problem. Clean and dry edge connector or replace. • Wet cartridge introduced moisture into edge connector. Clean and dry edge connector or replace. • Malfunctioning cartridge
6075	BP OUT LOW	• Bad user barometer offset entered • IRMA barometer malfunctioning, replace barometer.
6076	BP OUT HIGH	• Bad user barometer offset entered • IRMA barometer malfunctioning, replace barometer.
6400	ASIC WRITE FREQ DOESN'T READ OK	• IRMA malfunctioning, get instrument for repair
6401	2.5V REFERENCE OUT	• IRMA malfunctioning, get instrument for repair
6402	+5VA REGULATOR OUT	• IRMA malfunctioning, get instrument for repair
6403	-5VA REGULATOR OUT	• IRMA malfunctioning, get instrument for repair
6404	VBATSW SIGNAL OUT	• IRMA malfunctioning, get instrument for repair
6405	+VASW SIGNAL OUT	• IRMA malfunctioning, get instrument for repair
6406	INVALID HW PARAMETERS	• IRMA malfunctioning, get instrument for repair
6407	HW CONFIG BITS !=0	• IRMA malfunctioning, get instrument for repair
6500	SW UPLOAD CRC FAIL IN RAM--BOOTLOADER	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6501	SW UPLOAD CRC FAIL IN FLASH--BOOTLOADER	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6502	FLASH HEADER CHECKSUM FAIL--BOOTLOADER	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6503	NOVRAM VERSION MISMATCH--BOOTLOADER	• If error is associated with software loading, attempt software load again. • Lithium battery requires replacement. • IRMA malfunctioning, get instrument for repair
6504	BAD CRC OF NOVRAM IMAGE	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
6505	DUPLICATE NOVRAM VERSION	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6506	INCOMPATIBLE NOVRAM VERSION	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6507	SERIAL NUMBER MISMATCH	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6508	RAM TO NOVRAM MOVE FAILED	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6509	LANGUAGE 1 BAD CRC	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6510	LANGUAGE 1 MSG SET MISMATCH	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6511	LANGUAGE 2 BAD CRC	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6512	LANGUAGE 2 MSG SET MISMATCH	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6513	ERROR WRITING LANGS TO FLASH	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6514	ERROR COPYING NOVRAM	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6515	SYSTEM CLOCK READ FAIL	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6516	UNEXPECTED INTERRUPT	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6517	LANGUAGE INIT FAILURE	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6518	MEMORY ALLOCATION ERROR	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6519	MEMORY FREE ERROR	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6520	UNABLE TO READ HW CONFIGURATION	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6521	BAD TRUTH TABLE SYSTEM CHECKS	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
6523	NOVRAM VERSION MISMATCH	• If error is associated with software loading, attempt software load again. • Lithium battery requires replacement.

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
		• IRMA malfunctioning, get instrument for repair
8016	PRINTER_INOPERABLE	• IRMA printer is malfunctioning, get instrument for repair
8019	CORRUPTED_GLUC_QC_CONTROL	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
8020	CORRUPTED_QC_CONTROL	• If error is associated with software loading, attempt software load again. • IRMA malfunctioning, get instrument for repair
1	Glucose CPU RAM	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
2	Glucose Reserved 2	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
3	Glucose Not Fully Calibrated	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
4	Glucose Bad Gray Read	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
5	Glucose Battery Drift	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
6	Glucose Temperature Failure	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
7	Glucose Autoscale Error 660	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
8	Glucose Autoscale Error 940	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
9	Glucose Delta Error 660	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
10	Glucose Delta Error 940	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
11	Glucose ROM Checksum	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
12	Glucose No Strip Holder	Strip Holder gone or broken. Replace it.
13	Glucose Battery Regulator	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
14	Glucose No End Point	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
15	Glucose Dirty Meter (940)	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
16	Glucose Dirty Meter (660)	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
17	Glucose Auto Zero Delta	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
18	Glucose Reserved 3	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
19	Glucose Floating Pt Err 2	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
20	Glucose Dirty Meter (660 & 940)	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
21	Glucose No End Point (Temp)	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
22	Glucose Not Enough Blood	Not enough sample.
23	Glucose Blood On Wrong Side	Sample applied to wrong side of glucose strip.
24	Glucose Reserved 4	N/A
25	Glucose Strip Removed	Glucose strip removed before test could complete.
26	Glucose KS Error 660 (1)	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.

Code	ERROR DESCRIPTION	POSSIBLE CAUSES AND RECOMMENDATIONS
27	Glucose KS Error 940 (Last)	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
28	Glucose Floating Pt Error 3	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
29	Glucose Strip Jitters	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
30	Glucose Power Off in Test	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
31	Glucose ROM Checksum 3	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
32	Glucose KS Error 660 (2)	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
33	Glucose Autoscale Error	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
34	Glucose Floating Pt Error 4	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module.
35	Glucose Par Up Contact/No strip	• Glucose strip removed before test could complete. • Glucose strip contacts are dirty. • Internal failure of the SSP module. Error generated by Lifescan SW. Replace module
36	Glucose Contact/No strip	• Glucose strip removed before test could complete. • Glucose strip contacts are dirty. • Internal failure of the SSP module. Error generated by Lifescan SW. Replace module
37	Glucose Open Contact w/ Strip in	• Black tip of Glucose strip is damaged. • Glucose strip contacts are dirty. • Internal failure of the SSP module. Error generated by Lifescan SW. Replace module
38	Glucose Power Fail	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module
39	Glucose Watchdog Fail	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module
40	Glucose Stack Overflow	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module
41	Glucose Revision Error	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module
42	Glucose A/D Error	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module
43	Glucose Reserved 4	N/A
44	Glucose Reserved 5	N/A
45	Glucose Temp Fluctuation	Internal failure of the SSP module. Error generated by Lifescan SW. Replace module
46	Glucose Reserved 6	N/A
47	Glucose Reserved 7	N/A

Usage Log:

Recalling the Error Logs (these steps print the a log):

1. Power IRMA on
2. Select RECALL
3. Select LOGS
4. Select other errors (instrument, procedural, and sensor errors), or EQC errors (EQC and Temperature test errors).

The other errors log is a printable record of all messages given to the user during testing on the IRMA Æ Blood Analysis System. These messages include sensor errors, low battery messages, data downloading warnings, instrument errors, environmental warnings, and user induced procedural errors. This log is a troubleshooting tool, and is not intended for customer use. The following is a list of general error code classifications that stay consistent between software versions. Whenever possible, the specific IRMA error code numbers are kept the same between different software revisions to avoid confusion.

1xxx Environmental condition errors. Either the IRMAÆ or the cartridge is outside acceptable operating conditions.
2xxx User procedural errors. These errors include procedural problems such as premature removal of the cartridge, failure to perform some action within the allowed time period, or insertion of an incorrect card type.
3xxx Low battery and AC adapter messages.
4xxx Software upgrade notes and factory default messages.
5xxx Sensor errors. If the user is experiencing an undiagnosed occurrence of >10% of this type of error code, DMI technical support should be contacted.
6xxx Instrument and software errors. These are usually unrecoverable and DMI technical support should be contacted.
7xxx Not used at this time

8xxx Data Downloading messages and errors. These can be anything from warnings to the user to download data from IRMAÆ to actual downloading errors. The user should know if they were unable to download and at that point contact technical support. Otherwise, this message is a recording of the warning and should be ignored on the usage log.

IC (Insertion Count) is the number of cartridge insertions experienced by an IRMA. This number is also printed on the Other Errors log to allow calculation of a total error rate experienced by a user. To determine the number of insertions on an IRMA during a given time period, simply subtract the first IC number from the last IC number for the time period of interest.

To determine the sensor error rate, count the number of 5xxx errors on the usage log and calculate as follows:

% Sensor Errors = (# 5xxx Errors) / (# Sensor Insertions) * 100

APPENDIX H: Medical Usefulness Criteria

Health Care Financing Administration
Evaluation Criteria
(CLIA)

Analyte	Medical Usefulness Limits
pH	± 0.04 pH units
pCO2	± 5 mmHg or 8%, Whichever is greater
pO2*	± 5 mmHg or 7.5%, Whichever is greater
Sodium	± 4 mM
Potassium	± 0.5 mM
Ionized Calcium	No guidelines
Chloride*	± 5.0%
Urea	± 2.0 mg/dL or 9% whichever is greater
Hematocrit	± 6%
Glucose **(waived test)**	± 12 mg/dL or 20%, Whichever is greater
Glucose **(moderately complex)**	± 6 mg/dL or 10% Whichever is greater

* CAP criteria

APPENDIX I: Proficiency Survey Information

	Analyte	Survey Name
CAP	Blood Gas Sodium Potassium Ionized Calcium Chloride Glucose (cartridge method) BUN Conductive Hct	AQ
	CO-Oximetry (THb)	SO
	Glucose	WB (SureStepPro method)
Phone	**800-323-4040**	
AAB	Blood Gas	Blood Gases
	Electrolyte	Basic Chemistry
Phone	**800-234-5315**	
Accutest	Blood Gas	Blood Gas
	Blood Gas/Elyte	Blood Gas/Elyte
Phone	**800-356-6788**	

CAP: College of American Pathologists
AAB: American Association of Bioanalysts

APPENDIX J: REGULATORY MADE SIMPLE

	JCAHO	CAP	HCFA = CLIA
Personnel/Training	• Responsible individuals identified • Evidence of specific training with quarterly competency checks • Minimum high school diploma or equivalent	• Responsible individuals identified • Evidence of specific training with quarterly competency checks • Minimum high school diploma or equivalent • List of authorized personnel	• Responsible individuals identified • Evidence of specific training with quarterly competency checks • Minimum high school diploma or equivalent
Quality Control	• BG - one per 8 hr shift or 3 per 24 hrs of testing, whichever is greater • Lytes - two per 24 hrs of testing • Hct - two per 8 hr shift • Record remedial actions • Maintain records • Electronic QC ok	• BG - two per 8 hrs of testing • Lytes - two per 24 hrs of testing • Hct - two per 8 hr shift • Record remedial action • Maintain records • Electronic QC OK	• BG - one per 8 hr shift or 2 per 24 hrs of testing, whichever is greater • Lytes - 2 per 24 hrs of testing • Hct - two per 8 hr shift • Electronic QC ok
Quality Assurance	• Procedural manual • Covers policy and procedures, training requirements, specimen collection and preservation, instrument calibration, quality control and remedial action, equipment performance and evaluations, test performance.	• Procedural manual available in each area of testing • Manual contains specimen collection and preservation, instrument calibration, quality control and remedial action, test performance and maintenance records.	• Procedural manual containing instructions for performing tests, instructions for reporting results, calibration procedures, quality control procedures and requirements, and protocol for remedial actions
Linearity	• Linearity checks not required	• Evaluate per analyzer upon introduction of new method.	• Not required
Calibration Verification	• Follow manufacturers guidelines	• Required at a minimum every six months. IRMA does this before every test.	• Required every six months. IRMA does this before every test
Proficiency Testing	• Participate in program that meets federal and state regulations	• Must participate in CAP survey	• Participate in program that meets federal and state regulations
Certification	• Required for medicare	• Required	• Required
Inspections	• Every two years	• Every two years	• Every two years